

DATE OUT: 05/APR/1999

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D252488 REG./File Symbol No.: 63588-RR
PRODUCT NAME: Apogee Plant Growth Regulator

FROM: Shyam Mathur, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

S Mathur
04-05-99

TO: Cynthia Giles-Parker, PM 22
Fungicide Branch/RD(7505C)

INTRODUCTION:

The registrant has submitted the product chemistry data to support the registration of the subject product. The product contains Cyclohexanecarboxylic acid, 3,5-dioxo-4-(1-oxo-propyl)-, ion(1-) calcium, calcium salt(91%) as the active ingredient. This is a new chemical and the technical (common name, Prohexadione calcium) is under process of registration with the Agency. Apogee Plant growth regulator is a unique production management tool for apple and pear orchards that reduces vegetative growth allowing a balance between canopy development and fruit production. Apogee acts within the apple and pear trees to inhibit the biosynthesis of gibberellin, which is a natural plant hormone that regulates the cell elongation. Inhibition of gibberellin therefore reduces shoot growth.

SUMMARY OF FINDINGS:

1. The basic formulation CSF(dated 12-07-98) is filled out correctly and completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration. The data submitted corresponding to the guideline reference 61-1[830.1550] and 62-2[830.1750] satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

2. The alternate formulation CSF(dated 12-07-98) is filled out correctly and completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration. The data submitted corresponding to the guideline reference 61-1[830.1550] and 62-2[830.1750] does not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively. One of the inert ingredient used in the formulation is not cleared by the Agency.

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3. The data submitted corresponding to the guideline reference 61-2 [830.1650] and 61-3 [830.1670] satisfy the data requirements of 40CFR 158.165 and 158.167 respectively.
4. The data submitted corresponding to the guideline reference 62-3 [830.1800] satisfy the data requirements of 40CFR 158.180.
5. The data submitted corresponding to the guideline reference Physical state (830.6303), density (830.7300), pH (830.7000), Oxidation/Reduction (830.6314), Flammability (830.6315), Explodability (830.6316), Storage stability (830.6317), Viscosity (830.7100), Miscibility (830.6319), & Dielectric breakdown voltage (830.6321) satisfy the data requirements of 40CFR 158.190.
6. No data was submitted corresponding to Corrosion characteristics (830.6320) studies. This is considered as data gap.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the end-use product Apogee Plant growth regulator and concluded that:

1. All the product chemistry data requirements are satisfied in compliance with 40CFR Sec. 158.150 and are acceptable for the end-use product Apogee plant growth regulator, except for the alternate formulation CSF and corrosion characteristic study.
2. The registrant is required to submit the chemical composition of one of the inert ingredient used in the formulation, which must include the chemical name, CAS number, and percentages of each component of this inert ingredient. For the name of the inert ingredient, please refer to Confidential Appendix.
3. The registrant must submit the results of corrosion characteristic study for this end use product.
4. The registration of the end-use product Apogee plant growth regulator is subject to the registration of the Technical Prohexadione calcium. This new chemical is under process of review in the Agency.

PRODUCT CHEMISTRY REVIEW OF MP ☐ EP ☒

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PRODUCT NAME: Apogee Plant Growth Regulator

DATE: 04-05-99

1. Reviewer: S.B.Mathur 2. Company: K-I Chemical USA, Inc.
3. Type of Submission: Registration ☒ Reregistration ☐
 New ☒ Resubmission ☐ Amendment ☐ "ME-TOO" ☐
 Alternate Formulation ☐ Experimental Use Permit ☐
 Other (Specify) _____
4. If "Me-TOO" Registration, this product is ☐ is not ☐
 similar or substantially similar to EPA's Reg. No.: _____
 If not, comment in Confidential Appendix A on the differences
 between the registered and the new source where significant

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
 - Non-integrated formulation system..... ☒
 - Are all technical grade active ingredients used registered?
 - yes ☐ • no ☒ , If no, specify The technical Prohexadione calcium is under process of registration with the Agency.
 - Integrated formulation system..... ☐
 6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
 - 6(a) Formulation intended for food use under 40CFR§180.1001:
 - yes ☒ • no ☐ • Some are cleared, others are not ☐
 - Cleared under list: • c ☒ • d ☒ • e ☐
 - Are there any limitations for use as an inert under 40CFR §180.1001? • yes ☐ • no ☐ , If yes, specify _____
 - 6(b) Formulation intended for non-food use:
 - yes ☐ • no ☒ • Some are cleared, others are not ☐
 - 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).
 - yes ☐ • no ☐ • Some are cleared, others are not ☐
- If yes, the entire formulation is cleared under 21CFR§_____.

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 63-7, 63-12, and 63-15, respectively: • yes [X] • no []
8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)	% by weight		
	NC	UCL	LCL
Prohexadione Calcium Tech. (91%) under process of registration	30.2 (27.5)	31.1 (28.3)	29.3 (26.7)

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
 • yes [X] • no []
10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:
 • yes [X] • no []

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes [X] • no []
12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
 • yes [] • no [] • not applicable [X]
13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
 • yes [X] • no []

PRODUCT CHEMISTRY DATA (SERIES 61, 62, 63)

14. <u>Chemical IDs/Manufacture/ Analytical Information</u> New Guideline:830.--	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
1550.(61-1)Chemical Identity(CSF)B	Y	12-07-98
(CSF)A	U	12-07-98
1600.(61-2a) Beginning Materials	Y	447252-01
1620.(61-2b) Formulation Process		
1670.(61-3) Discussion of Impurities	Y	" "
1700.(62-1) Preliminary Analysis	NA	
1750.(62-2) Certified Limits(CSF)B	Y	12-07-98
(CSF)A	U	12-07-98
1800.(62-3)Enforcmnt. of Anal.Method	Y	447252-01

15. <u>Physical/Chemical Properties</u> New Guideline No. 830.---	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
6303.(63-3)Physical State	Y	solid	447252-05 447252-04
7300.(63-7)Density/Bulk Den.	Y	0.62 kg/L	" "
7000.(63-12) pH	Y	6.83/6.59	" "
6314.(63-14)Oxid/Red Action	Y	None	" "
6315.(63-15a)Flamm.-Flsh Pt.	NA		" "
6315.(63-15b) Flame Exten.	NA		
6316.(63-16)Explodability	Y	non-explosive	" "
6317.(63-17)Storage Stablty.	PR 92-5		
7100.(63-18)Viscosity	NA		
6319.(63-19) Miscibility	NA		" "
6320.(63-20)Corrosion Charac	G		
6321.(63-21)Dielec.Bkd.Vltg	NA		

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable;
G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.


CONFIDENTIAL APPENDIX

PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]

DP BARCODE No.: D252488 REG./File Symbol No.: 63588-RR

PRODUCT NAME: Apogee Plant growth regulator

Name of the inert ingredient not cleared in the alternate formulation CSF by the Agency:


Provide the complete chemical composition with chemical names, CAS numbers, and percentages of each component of this inert ingredient.